

Notice of Allowability

Application No.

09/655,667

Examiner

Natalie A. Pass

Applicant(s)

BRIEGS ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Decision by the Board of 6 June 2005.
2. ☒ The allowed claim(s) is/are 1-17, 19-38 and 43-45.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☒ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Decision by the Board filed 6 June 2005.

Claims 1-17, 19-38, and 43-45 are pending.

Allowable Subject Matter

2. The following is an examiner's statement of reasons for allowance:

Claims 1-17, 19-38, and 43-45 are allowed. The following is an examiner's statement of reasons for allowance:

Independent claims 1, 19, and 43 are directed to a clinical trial management system comprising a user processor and main processor running a program that designs and tracks at said user processor a clinical trial through access by said user processor to at least one software template in said main database and modification of the template for formulating a new clinical trial and also running a program that designs a clinical trial and the input of information with regard to the completion of tasks forming a protocol for the clinical trial and tracks the completion of the tasks at said user processor.

The closest prior art of record, Colon et al., U.S. Patent Number 5, 991, 731, teaches a main database of information concerning prior clinical trials and resources available to conduct future clinical trials. However Colon does not teach said user processor and main processor

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running a program that designs and tracks at said user processor of a clinical trial through access by said user processor to at least one software template in said main database and modification of the template for formulating a new clinical trial. DeBusk et al., U.S. Patent Number 5, 995, 937, teaches the protocol being stored in said main database in the form of a software template, but does not teach tracking a clinical trial or modifying a template for formulating a new clinical trial or tracking the completion of the tasks.

In the decision by the Board of Patent Appeals and Interferences mailed 6 June 2005, the prior rejections of claims 1-17, 19-38, and 43-45 were reversed. The reason for the reversal of system claims 1, 19, and 43 was, as noted by the Board at pages 4-5 of their decision mailed 6 June 2005, that a *prima facie* case of obviousness has not been made by the Examiner, and, as noted by the Board at pages 8-9 of their decision, that the closest prior art references, Colon et al., U.S. Patent Number 5, 991, 731, and DeBusk et al., U.S. Patent Number 5, 995, 937, both alone and in combination, fail to disclose designing or tracking a clinical trial or modifying a template for formulating a new clinical trial and "a program that designs a clinical trial and tracks the completion of tasks forming a protocol for the clinical trial."

Claims 2-17, 20-38, and 44-45 incorporate the features of claims 1, 19, and 43 through dependency, and are also allowed for the same reasons given above.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied reference (WO 98/49647) teaches the environment of clinical trials design, however fails to disclose all the limitations claimed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (571) 272-3600.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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7. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington D.C. 20231

or faxed to: **(571) 273-8300.**


For informal or draft communications, please label
"PROPOSED" or "DRAFT" on the front page of the communication
and do NOT sign the communication.

After Final communications should be labeled "Box AF."



Natalie A. Pass

October 17, 2005



JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
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